REMARKS

Status of the Claims

Claims 1-4, 6, 7, 9-15, 17, 18, 33-36, and 42-52 were pending in the present application.

Claims 1-4, 6, 7, 9-15, 17, 18, 33-36, and 42-52 were rejected

By way of this amendment, claims 1, 4, 6, 7, 9-12, 15, 17, 18, 33 and 42-44 have been amended, claims 2, 3, 13, 14, 34, 35, 40, 41 and 45 have been canceled, and new claims 53-55 have been added.

Upon entry of this amendment, claims 1, 4, 6, 7, 9-12, 15, 17, 18, 33, 36, 42-44, and 46 - 55 will be pending.

Summary of the Amendment

Claims 1, 12 and 33, have been amended to define specific embodiments of the invention more precisely. Support for the amendments appears throughout the specification and claims as originally filed.

Claims 4, 6, 7, 9-11, 15, 17, 18 and 42-44 have been amended to be more consistent with the claims from which they depend and more expressly recite that the compositions are pyrogen free. Support for the amendments appears throughout the specification and claims as originally filed.

New claims 53-55 have been added to refer to embodiments of the invention. Support for the amendments appears throughout the specification and claims as originally filed.

No new matter has been added.

Claim Objections

Claims 1-4, 6-7, 9-15, 17-18, 33-36 and 40-52 stand rejected as reciting non-elected subject matter. Applicants respectfully note that each of the claims read on the elected species. Upon concluding that the elected species is allowable, Applicants respectfully request that the generic claims which read on the elected species and a reasonable number of non-elected species be examined and allowed.

Claim Rejections Based Upon 35 U.S.C. §112, first paragraph

Claims 1-4, 6-7, 9-15, 17-18, 33-36, and 40-45 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly failing the enablement requirement. The Office asserts that it would have required undue experimentation to practice the scope of the invention as claimed. The Office asserts that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. (Office Action Response, page 3).

As amended, the claims no longer refer to compositions and methods in which the immunogen is a cancer or auto-immune disease associated antigen. Applicants respectfully request that the rejection based upon 35 U.S.C. §112, first paragraph, be withdrawn.

Applicants respectfully note that the Office has asserted, through the course of its reasoning, that the claims "continue to broadly encompass any route of administration." (Office action, page 5). This line of reasoning is not correct. Applicants amended the independent method claims of the application to recite "by intramuscular injection" in its response of July 10, 2007.

In view of the evidence of record, those having ordinary skill in the art would conclude that the claimed invention is enabled. Applicants respectfully request that the rejection of the claims under 35 U.S.C. § 112, first paragraph, be withdrawn.

Claim Rejections Based Upon 35 U.S.C. §102

Claims 1–3, 6, and 12 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent number 6,417,328 (hereinafter "Alnemri"). Applicants respectfully disagree and request that the rejection based upon 35 U.S.C. § 102(e) be withdrawn.

The Office has repeatedly asserted that Alnemri anticipates the claimed invention by citing, in particular, column 22, which refers to "expressible nucleic acids encoding DR5." The composition claims of the current invention do not recite "expressible nucleic acids of DR5." The Office maintains that LacZ is a "bacterial pathogen antigen."

Claim 1 recites "a pyrogen-free composition" comprising a plasmid comprising a nucleotide sequence that encodes an immunogen operably linked to regulatory elements and a nucleotide sequence that encodes an immunomodulating protein operably linked to regulatory elements wherein immunomodulating protein is DR5 and wherein the immunogen is a pathogen antigen. Claims 2 and 3 have been canceled. Claims 6 and 12 have been amended to expressly recite "a pyrogen-free composition"

Alnemri does not recite "compositions that are pyrogen free." Nowhere in Alnemri do authors teach or suggest preparing pyrogen free material. Nowhere in Alnemri do authors teach or suggest a pyrogen free composition that comprises one or more plasmids which comprise a nucleotide sequence that encodes DR5 and a nucleotide sequence that encodes a pathogen immunogen. As such, Alnemri fails to the recite all of the elements of the claims.

Alnemri does not disclose the subject matter set forth in the claims. In view of the foregoing, Applicants respectfully request that the rejections of claims 1 - 3, 6, and 12 under 35 U.S.C. § 102(e) as being anticipated by Alnemri be withdrawn.

Claim Rejections Based Upon 35 U.S.C. §103

Claims 1–3, 6, and 12 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Alnemri in view of US Pat. No. 5,693,622 (hereinafter "Wolff").

Claim 1 recites "a pyrogen-free composition" comprising a plasmid comprising a nucleotide sequence that encodes an immunogen operably linked to regulatory elements and a nucleotide sequence that encodes an immunomodulating protein operably linked to regulatory elements wherein immunomodulating protein is DR5 and wherein the immunogen is a pathogen antigen. Claims 2 and 3 have been canceled. Claims 6 and 12 have been amended to expressly recite "a pyrogen-free composition"

Alnemri does not recite "compositions that are pyrogen free." Nowhere in Alnemri do authors teach or suggest preparing pyrogen free material. Nowhere in Alnemri do authors teach or suggest a pyrogen free composition that comprises one or more plasmids which comprise a nucleotide sequence that encodes DR5 and a nucleotide sequence that encodes a pathogen immunogen. Alnemri does not disclose that DR5 has immunomodulatory activity. Alnemri does not disclose any basis for using coding sequences of DR5 and immunogens in combination in the context of a pharmaceutical composition. Nothing in Alnemri teaches the combination of coding sequences of DR5 and immunogens in a pharmaceutical composition.

Wolff discloses delivery of DNA vaccines but neither teaches nor suggests DR5 as an immunomodulatory co-agent.

Nothing in either Alnemri or Wolff, alone or in combination, provides any reason why one skilled in the art would make a pyrogen free composition that comprises coding sequences of DR5 and immunogens. The combination in a pyrogen free composition is not obvious. There is nothing in the art that would suggest the combination based upon any teaching or knowledge in the art. Applicants' discovery that DR5 has immunostimulatory activity when delivered as part

of a DNA vaccine was not obvious. Absent such a discovery, one skilled in the art would not combine the references to produce the claimed invention.

Applicants respectfully request that the rejection based upon 35 U.S.C. §103(a) be withdrawn.

Conclusion

Claims 1, 4, 6, 7, 9-12, 15, 17, 18, 33, 36, 42-44 and 46 – 55 are in condition for allowance. A notice of allowance is earnestly solicited. The Commissioner is hereby authorized to charge any deficiencies of fees and credit of any overpayments to Deposit Account No. 50-0436.

Respectfully submitted,

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